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10/775,501	02/09/2004	Leena Peltonen	021825-006300US	2308

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EXAMINER	
CHO, DAN SUNG C	
ART UNIT	**PAPER NUMBER**
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,501	PELTONEN ET AL.	
	Examiner	Art Unit	
	Dan-Sung C. Cho	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-75* is/are pending in the application.

4a) Of the above claim(s) *53-54, 57-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-52,55,56 and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/7/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 41-75 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group I, Claims 41-52, 55-56 and 75 and SEQ ID NO: 5 for claim 1 in the paper filed 11/13/2006 is acknowledged. Because claim 41 does not have SEQ ID NO:5, the elected sequence is SEQ ID NO:1, a smaller fragment of SEQ ID NO: 5. The traversal is on the grounds that SEQ NOs: 3 and 5 differ by a single nucleotide polymorphism. It is noted that although SEQ ID NOs: 3 and 5 were restricted form each other as drawn to different inventions (not different species) in the previous restriction requirement, because the sequences only differ by a single polymorphism, the restriction requirement between SEQ ID NOs: 1 and 3 has been changed to election of species. Restriction between SEQ ID NOs: 1 and 5 is withdrawn. The restriction requirement for claim 56 to Group VIII is withdrawn. Claim 56 has been examined with Group I claims. The restriction to the variant form of the human LPH at position "-13910" is made FINAL.

The instant claims are generic to the following disclosed patentably distinct species: LPH wild-types and variant promoter sequences at position "-13910". The species are independent or distinct because these sequences are structurally and functionally distinct.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species, SEQ ID NO: 3 which depends from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). Applicant's arguments that SEQ ID NOs:1/5 and 3 should be rejoined with the elected species is not found persuasive because the sequences are structurally and functionally distinct, unobvious over each other, and require a different search.

Claims 41 and 42, directed to a position "-22018", 51-52 (parts) 53-54, 55 (in part directed to position "-22018") and 57-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 42, 47 and 55, directed to position –13910, are withdrawn from further consideration as being drawn to nonelected species. Therefore, an action on the merits of claims 41, 43-46, 48-52, 56 and 75, directed to SEQ ID NO: 1, and position –13910 is set forth below.

Priority

3. This application is a continuation of PCT/EP02/08963 and claims benefit of 60315955 filed 8/31/2001, and priority to EPO EP01119377.8 filed on 8/10/2001 and EPO EP01119528.6 filed on 8/14/2001. It is noted, however, that applicant has not filed a certified copies of EPO EP01119377.8 and EPO EP01119528.6 as required by 35 U.S.C. 119(b). Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d), a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action. Therefore the priority date of the application is 8/31/2001.

Claim Objections

4. Claims 41-42 are objected to because of the following informalities: The claims contain references to sequence and SNP sites described in figures. MPEP 2173.05(s) states "Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." In the instant case it would be possible to refer to the claimed sequences and SNP sites using proper sequence identifiers and phraseology. In addition, claim 41 contains misspellings: "adult-typo" and "SEQ ID NQ:1". Appropriate correction is required. .

Applicant is advised that should claims 49 and 50 be found allowable, claims 49 and 50 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 51 and 52 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 51 recites "the vector of claim 46"; however, claim 46 recites "A nucleic acid molecule".

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 41, 43-46, 48-52, 56 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41, 45, 50 recite the limitation "-13910". It is unclear what position the "-13910" is relative to. SEQ ID NO: 1 does not contain any position designated as "-13910". In addition, claim 41 recites "A nucleic acid molecule comprising of a 5' portion of an intestinal lactase-phlorizine (LPH) gene" but also recites that the molecule is selected from the group consisting of a nucleic acid that has "a position corresponding to position –13910 5' from the LPH gene". However, it is not clear what position number 1 is. The number 1 position could refer to either the first ATG, that is the translation start site, or the transcription start site, which are not normally the same. Accordingly, without a reference point, the recitation of –13910 is indefinite. Therefore it is unclear what "-13910" position is in LPH gene 5' portion.

Claim 41 is indefinite because of the recitation "depicted in Fig. 4 and comprised in the sequence as depicted in Fig. 8". It is not clear whether the additional recitations to figures are alternative claim embodiment or not.

Claim 41 is further indefinite because of the recitation "5' portion of an LPH gene"; however at page 6, the specification teaches that the disclosed variants "are at a

considerable distance from the LPH gene". Accordingly, as the variant at position –13910 does not appear to be in the LPH gene, given the guidance in the specification, the metes and bounds of "a 5' portion of a gene" is unclear as it cannot be determined which sequences are within the scope of the claim. For example, would a sequence which comprises the indicated position, but not residing in the LPH gene be within the scope of the claim or not. Additionally, the specification does not teach the boundaries of the LPH gene, such that the artisan would be able to determine which sequences were within LPH gene and which were not.

Claims 51 and 52 are indefinite because claim 51 recites the limitation "the vector of claim 46". There is insufficient antecedent basis for this limitation in the claim. Claim 46 does not recite any "vector".

Claim Rejections - 35 USC § 112- Enablement- Scope

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 51 and 52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated non-human host cells, does not reasonably provide enablement for any host organism transformed with SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the

enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

The instant claims encompass any non-human host transformed with a vector that contains a nucleic acid comprising SEQ ID NO: 1 including transgenic animals, plants, and cells used for gene therapy. The invention is in a class of invention, which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Guidance in the Specification.

The specification discloses isolation of cells for isolating DNA and genotyping purposes. However, the specification does not disclose any other *in vivo* host or host transformed with SEQ ID NO:1. The specification contemplates gene therapy and phenotyping studies (page 13, line 38 to page 14, line 3). However, the specification does not provide any method of phenotype studies or gene therapy or disclose host cells *in vivo* with any particular phenotype or therapeutic effects comprising the claimed nucleic acids.

The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention.

The unpredictability of the art and the state of the prior art

The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art.

Holschneider (Int J. Development. Neuroscience 18:615-618, 2000) discuss various factors that contribute to the resulting phenotype of transgenic mice, including compensatory systems, which may be due to the differential expression of another gene, which may be regulated by the downstream product of the ablated gene, as well as the variability in phenotypic characterization due to particular mouse strains (see, p. 616, column 1).

Leonard (Immunological Reviews, 148:97-114, 1995) discloses mice with a disruption in the Yc gene that was intended to be a model for X-linked severe combined immunodeficiency (XSCID), but display a variety of unexpected traits (Abstract).

Griffiths (Microscopy Research and Technique, 41:344-358, 1998) taught that, despite a known role for the PLP gene based on spontaneous mutations in the gene, the knockout mouse failed to display any of the expected phenotypes (page 350, last paragraph). Thus, at the time of filing, the art exemplifies the unpredictability of correlating phenotypes in vivo with transfection of particular DNA sequences.

Working Examples

The specification has no working example of host organisms transformed with the recited DNA for gene therapy or phenotype studies other than isolated biopsies human cells used for DNA isolation and genotyping purposes.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters, which would have to be studied such as host strain variations, environmental genetic interactions, gene dosage factors, and epigenetic. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In conclusion, the disclosed information from the as-filed application plus the state of the prior art is not deemed sufficient to reasonably convey to one of ordinary skill in the art that the Specification is reasonably enabling for the full breadth of the claim at the time the invention was made. Because of lack of working examples, insufficient guidance and direction in the specification, the inherent unpredictability in the art, the state of the art and the nature of the invention, one of ordinary skill in the Art

to would be required to perform a large amount of experimentation to make and/or use the invention claimed by the Applicant.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 41, 43-46, 48-52, 56 and 75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure.

With regard to claim 41 (a) and 46, the specification does not teach any nucleic acid comprising a SEQ ID NO:1 sequence or any nucleic acid 20+ nucleotides in length whose complementary sequences would hybridize to a SEQ ID NO:1 sequence and "contributing to or indicative of adult-type hypolactasia" other than the human LPH gene. Nucleic acid sequences, which hybridize, can have number of variations and still hybridize to SEQ ID NO: 1. "Stringent conditions" encompass low, medium or high stringencies, which allow for variation between sequences that hybridize. Claims 41 and 46 are drawn to any nucleic acid comprising SEQ ID NO:1 or any nucleic acid 20+

nucleotides in length whose complementary sequences can hybridize to any sequence of SEQ ID NO: 1. The claim recites that it is a 5' portion of the LPH gene, however at page 6, the specification teaches that the variants are "at a considerable distance from the LPH gene", therefore it appears that the disclosed variant is not actually in the LPH gene. Accordingly, specification does not appear to provide evidence of possession of a 5' portion of the LPH gene which contains the SNP at –13910, but rather teaches only a portion of a genomic sequence which contains the SNP, that is SEQ ID NOs: 5 and 1.

Claim 45 is drawn to any nucleic acid of 14+ nucleotides in length whose sequences are comprised of SEQ ID NO: 1 sequences with a cytosine or any nucleic acid 14+ nucleotides in length whose complementary sequences can hybridize under any (low, medium and high) stringency conditions to any sequences of SEQ ID NO: 1. Therefore the claim encompasses a large genus of sequences for which the specification teaches but a single species of SEQ ID NO:1.

With regard to claim 46, the claim encompasses a large genus of sequences that has any complementary sequences of any of the already large genus of nucleotide sequences encompassed by claim 41. The term "complementary" is not limited to the "complete complement". Sequences can have degrees of complimentary to each other and still hybridize to each other.

Claims 49 and 50 are drawn to any nucleic acid whose sequences are comprised of SEQ ID NO:1 with a cytosine or its complementary sequences which can hybridize under any (low, medium and high) stringency conditions to any sequences of SEQ ID NO: 1 or its complementary sequences. Therefore the claim encompasses an

enormous genus of sequences for which the specification teaches but a single species of SEQ ID NO:1.

The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "hybridizes under stringent condition" is insufficient to describe the genus because the skilled artisan would not be able to envision what other species would have the claimed function. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only SEQ ID NO: 1 as species is not representative of the variants of the genus and is insufficient to support the claim.

Conclusion

Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 41, 43-46, 48, 51-52, 56 and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by Ye (Ye et al., US Patent No. 6492155, filed on 3/9/2001).

With regard to claim 41(c), Ye teaches SEQ ID NO: 3, which has 50.3% sequence identity from positions 89513 to 89663 that align to positions 15-165 of the instant application SEQ ID #3. SEQ ID NO: 3 Ye teaches has a cytosine at position 84 which appears to corresponds to "–13910 5' from the LPH gene" because Figure 4 of the instant application indicates a lower case "c" as the sequence corresponding to the "–13910 5' from the LPH gene" (Figure 3 of Ye; alignment provided).

With regard to claim 43, SEQ ID NO: 3 Ye teaches is a human genomic DNA sequences (column 7, lines 15-20).

With regard to claim 44, SEQ ID NO: 3 Ye teaches is a part of human protein kinase gene sequences (column 4, lines 49-53; column 7, lines 14-43; Figure 2D).

With regard to claim 45, SEQ ID NO: 3 Ye teaches has 76 nucleotides identical to the instant application SEQ ID NO: 3 including a cytosine at position 84 which corresponds to –13910 "5' from the LPH gene" (Figure 3; alignment provided).

With regard to claim 46, because SEQ ID NO: 3 Ye teaches is a genomic DNA sequences with a sequence identity of more than 50% to the instant application SEQ ID NO: 3, Ye also teaches a complementary sequences to the SEQ ID NO: 3. A human genomic DNA sequences are double stranded but usually written one of the strands;

therefore SEQ ID NO: 3 Ye teaches also teaches the complementary sequences of SEQ ID NO; 3.

With regard to claims 48, Ye teaches various vectors including plasmid, single or double stranded phage, a single or double stranded RNA or DNA viral vector, or artificial chromosome, such as a BAC, PAC, YAC, OR MAC (page column 31 lines 1-11 and claims 6-9).

With regard to claims 51-52, Ye teaches various host cells with a vector that contains SEQ ID NO:3 sequences, including prokaryotic cells, lower eukaryotic cells such as yeast, other eukaryotic cells such as insect cells, and higher eukaryotic cells such as mammalian cells (column 33, lines 42-46).

With regard to claim 56, the instant claim was grouped with Group I, drawn to DNA, vector, host cell, composition and a kit, as being limited to composition by the examiner in a paper filed on 10/11/2006. No weight is given in the instant rejection for diagnostic aspect of the instant claim because it is intended use, and is therefore given no patentable weight. Therefore, recitation of "diagnostic" does not distinguish the claimed nucleic acid molecules from the teachings of Ye. The instant claim does not limit claim 41 to distinguish it from a composition of nucleic acid in claim 41, which is anticipated by Ye.

With regard to claim 75, the instant specification does not define the term "kit" to include any additional structural requirement to distinguish it from a composition. Therefore the claim has been given its broadest reasonable interpretation to encompass a composition of a nucleic acid of claim 41, which is anticipated by Ye.

9. Claims 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (Brennan, US Patent 5474796, December 12, 1995).

Claims 49 and 50 are drawn to a primer or primer pair that hybridizes to a nucleic acid molecule with the –13910 position sequence of SEQ ID NO: 1 or its complement. Therefore, the claims are given the broadest reasonable interpretation to encompass sequences within SEQ ID NO: 1 or its complementary sequences. Brennan teaches an array which contains every possible 10-mer oligonucleotide (see Column 9, lines 49-50). The claims encompass a large genus of polynucleotides from within SEQ ID NO: 1 or its complements which are anticipated by the disclosure of Brennan.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ye in view of Ahern (Ahern et al., The Scientist 1995, 9: 20).

For the purpose of this rejection, a kit is interpreted as a package with the claimed nucleic acid. With regard to claim 41 and 46, Ye teaches SEQ ID NO: 3, which has 50.3% sequence identity from positions 89513 to 89663 that align to positions 15-165 of the instant application SEQ ID #3. Ye teaches that the SEQ ID NO: 3 has a cytosine at position 84 which corresponds to –13910 5' from the LPH gene.

Ye does not teach a kit packaged with the claimed nucleic acid.

However, Ahern teaches kits to deliver to researchers prepared chemicals (page 1 of the copy (page 20 on the original), last paragraph). Ahern teaches included in the kit is a sheet of instructions (page 1, First Figure, Hot seller, instruction sheet is in the background). Ahern teaches although the cost of doing science tends to go up with use of kits the volume of data output has done up and therefore there is a good return on your investment when using kits (page 4 of the copy, lines 19-20).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to package the nucleic acid Ye teaches in a kit as taught by Ahern. The ordinary artisan would want to incorporate the nucleic acid into a kit because Ahern teaches "premade biochemicals and reagents offer scientist the opportunity to better manage their time, putting these products all together in kits take the convenience one step further." (Ahern p. 24).

Conclusion

12. No claims allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Dan-Sung C. Cho whose telephone number is (571) 272-9933. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). The Central Fax Number for official correspondence is (571) 273-8300.

Dan-Sung C. Cho
Examiner

Jehanne Sitton
JEHANNE SITTON
PRIMARY EXAMINER
1/22/07

SEQUENCE ALIGNMENT BETWEEN SEQ ID NO: 1 OF 10/775,501
AND
SEQ ID NO:3 OF 09/801,876

US-09-801-876B-3
; Sequence 3, Application US/09801876B
; Patent No. 6492155
; GENERAL INFORMATION:
; APPLICANT: YE, Jane et al
; TITLE OF INVENTION: ISOLATED HUMAN KINASE PROTEINS, NUCLEIC
; TITLE OF INVENTION: ACID MOLECULES ENCODING HUMAN KINASE PROTEINS, AND USES
; TITLE OF INVENTION: THEREOF
; FILE REFERENCE: CL001160
; CURRENT APPLICATION NUMBER: US/09/801,876B
; CURRENT FILING DATE: 2001-03-09
; NUMBER OF SEQ ID NOS: 8
; SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 3
; LENGTH: 148567
; TYPE: DNA
; ORGANISM: Human
; FEATURE:
; NAME/KEY: misc_feature
; LOCATION: (1)...(148567)
; OTHER INFORMATION: n = A,T,C or G
US-09-801-876B-3

Query Match 17.2%; Score 31; DB 3; Length 148567;
Best Local Similarity 50.3%; Pred. No. 12;
Matches 76; Conservative 0; Mismatches 75; Indels 0;
Gaps 0;

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Qy         15 AAAAATGTACTTAGACCCTACAATGTACTAGTAGGCCTCTGCGCTGGCAATACAGATAAG 74
              ||| |||| || ||  |||| ||  ||  |||  |  |       | | |  || |
Db      89513 AAATATGTGCTGAGTTCCTAGAAATTAAAAGTGAGAATGAAAAAAAGAATCAATGAAAGT
89572
                                 ⇓
Qy         75 ATAATGTAGcCCCTGGCCTCAAAGGAACTCTCCTCCTTAGGTTGCATTTGTATAATGTTT 134
              | | |  | | || || |   ||  ||  ||  | | |   || |  | || ||| | |
Db      89573 ACAGTAGATcTCCCGGACAAGGAGAGACCATCTGCATAAAACTGAAGATATAAAATATGT
89632

Qy        135 GATTTTTAGATTGTTCTTTGAGCCCTGCATT 165
              || ||     || |   || |   || ||||
Db      89633 GACTTCCTACTTTTAGATTAAAATCTACATT 89663
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